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	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	09/743,731	04/25/2001	John Smit	08106-004001	7587
	7590 02/23/2005			EXAMINER	
		iGiGLIO, ESQ. TT,MURPHY & PRES	SER	STEADMAN, DAVID J	
400 GARDEN CITY PLAZA GARDEN CITY, NY 11530				ART UNIT	PAPER NUMBER
				1652	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

·····		Application No.	Applicant(s)					
		09/743,731	SMIT, JOHN					
	Office Action Summary	Examiner	Art Unit					
		David J Steadman	1652					
Period fo	The MAILING DATE of this communication apported by Reply	pears on the cover sheet with the	correspondence address					
THE - External after of the control	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.7 SIX (6) MONTHS from the mailing date of this communication. It is period for reply specified above is less than thirty (30) days, a reput of the provision of	I36(a). In no event, however, may a reply be by within the statutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS fro c, cause the application to become ABANDON	timely filed ays will be considered timely. m the mailing date of this communication. NED (35 U.S.C. § 133).					
Status								
1)⊠	Responsive to communication(s) filed on 31 J	anuary 2005.						
2a)□	This action is FINAL . 2b)⊠ This	s action is non-final.						
3)[rosecution as to the merits is 453 O.G. 213.							
Disposit	ion of Claims							
5)	Claim(s) 1-6 and 9-12 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) 1-6 and 9-12 is/are rejected. Claim(s) is/are objected to.							
Applicat	ion Papers							
9)□	The specification is objected to by the Examine	er.						
10)[_	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. S	ee 37 CFR 1.85(a).					
1,1) 🔲	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	· · · · · · · · · · · · · · · · · · ·	•					
Priority (under 35 U.S.C. § 119	•						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ■ All b) ■ Some * c) ■ None of: 1. ■ Certified copies of the priority documents have been received. 2. ■ Certified copies of the priority documents have been received in Application No 3. ■ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
Attachmen	t(s)							
	ce of References Cited (PTO-892)	4) Interview Summa						
3) 🔲 Infon	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date	Paper No(s)/Mail 5) Notice of Informal 6) Other: Appendix A	Patent Application (PTO-152)					

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DETAILED ACTION

Status of the Application

- [1] In view of the new ground of rejection presented below, the finality of the last Office action is withdrawn. See MPEP § 706.07(e).
- [2] Claims 1-6 and 9-12 are pending in the application.
- [3] Applicant's amendment to the claims, filed January 31, 2005, is acknowledged and has been entered into the record. This listing of the claims replaces all prior versions and listings of the claims.
- [4] Applicant's arguments filed January 31, 2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

- [6] In view of applicant's amendment to correct antecedent basis in claim 9, the rejection of claims 9-12 under 35 USC § 112, second paragraph, in the Office action mailed 10/28/2004 is withdrawn.
- [7] Claims 1-6 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 (claims 2-6 dependent therefrom) and 9 (claims 10-12 dependent therefrom) are indefinite in the recitation of "Caulobacter crescentus S-layer protein" (claim 1) or "an S-layer protein of said Caulobacter crescentus" (claim 9) for at least the following reasons.

While the specification fails to provide a definition of a "Caulobacter crescentus" S-layer protein," it discloses the sequence of SEQ ID NO:5, which is considered to be a "Caulobacter crescentus S-layer protein." Also, the prior art discloses an amino acid sequence that, while being structurally distinct from the Caulobacter crescentus S-layer protein of SEQ ID NO:5 (See Appendix A), is considered to be a Caulobacter crescentus S-layer protein. However, upon further consideration of the terms, it is unclear to the examiner as to how a skilled artisan distinguishes a "Caulobacter crescentus S-layer protein" from any other S-layer protein as the specification fails to which characteristics of an S-layer protein or proteins from Caulobacter crescentus that are necessary for inclusion of a protein which is distinct in sequence from other S-layer proteins, e.g., S-layer proteins that are isolated from non-Caulobacter crescentus microorganisms. In other words, what characteristics distinguish the scope of proteins that are considered to be included in the terms "Caulobacter crescentus S-layer protein" and "an S-layer protein of said Caulobacter crescentus" from other S-layer proteins that are not considered to be encompassed by the terms?

Second, it appears that applicants intended scope of *Caulobacter crescentus* S-layer proteins is different from the scope of *Caulobacter crescentus* S-layer proteins based on the examiner's previously stated interpretation of the term. During

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prosecution, the examiner has set forth a definition of the term "Caulobacter crescentus" S-layer protein" as encompassing any polypeptide sequence that includes a secretion signal (see, e.g., p. 4, middle and p. 6, bottom of the Office action mailed 10/28/04), including mutants and variants of SEQ ID NO:5, generated by, for example, chemical or UV mutagenesis of a strain of Caulobacter crescentus. Applicants do not dispute this definition. However, applicant's arguments presented in the instant response (see, e.g., p. 6, top of the instant response) indicate that the scope of proteins that are encompassed by the terms are intended as those that are "only from Caulobacter crescentus," which is different in scope from the scope of proteins encompassed by the examiner's interpretation of the term Caulobacter crescentus S-layer protein.

At least for these reasons, it is unclear as to the scope of proteins that are encompassed by the terms "Caulobacter crescentus S-layer protein" and "an S-layer protein of said Caulobacter crescentus."

It is suggested that applicants clarify the meaning of the terms.

Upon reconsideration of the examiner's interpretation of the terms, it appears that this definition may not be reasonable in light of the specification. As the specification does not provide specific disclosure that the terms are meant to encompass mutants and variants, the examiner vacates the previous interpretation of the terms, *i.e.*, any polypeptide sequence that includes a secretion signal, in favor of the following interpretation of "Caulobacter crescentus S-layer protein" and "an S-layer protein of said Caulobacter crescentus:" S-layer proteins that are isolated from Caulobacter crescentus.

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Claim Rejections - 35 USC § 112, First Paragraph

[8] The written description rejection of claims 1-6 and 9-12 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and for the reasons stated below.

RESPONSE TO ARGUMENTS: Applicant argues the genus of first components of the fusion protein are "fairly limited" as Applicant is not claiming S-layer proteins from any *Caulobacter*, but only from *C. crescentus*. Applicant argues there is no evidence that S-layer proteins from different strains of *C. crescentus* are so widely variant that SEQ ID NO:5 is not representative of the genus, citing Exhibit A as evidence thereof. Applicant further argues that even assuming "some differences" in the amino acid sequences of S-layer proteins from different *C. crescentus* strains, there is no basis for the examiner to conclude that the disclosed fragments of SEQ ID NO:5 are not representative of all species of *C. crescentus* S-layer protein fragments as encompassed by the claims for practicing the claimed methods.

Applicant's argument is not found persuasive. The examiner maintains the position that the disclosed representative species of S-layer protein fragments of a single polypeptide, *i.e.*, amino acids 622-1026, 690-1026, 784-1026, 892-1026, and 907-1026 of SEQ ID NO:5, fail to describe all species of fragments of a *Caulobacter crescentus* S-layer protein which comprise a secretion signal as encompassed by the claims. The examiner acknowledges that applicant's claims are limited to fragments of a *Caulobacter crescentus* S-layer protein. However, the genus of *Caulobacter crescentus* S-layer proteins is not adequately described at least for the following two reasons.

A 111 '1 4050

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First, as stated above, it is not clear to the examiner as to those characteristics that distinguish the subgenus of recited Caulobacter crescentus S-layer proteins from the larger genus of S-layer proteins from any microorganism. MPEP § 2163 states (citing Amgen, 927 F.2d at 1206, 18 USPQ2d at 1021), "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials." Also, citing Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606, the CAFC UC California v. Eli Lilly, (43 USPQ2d 1398) stated, "[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials." In this case, the specification fails to define a Caulobacter crescentus S-layer protein such that a skilled artisan can distinguish the subgenus of Caulobacter crescentus S-layer proteins from the larger genus of S-layer proteins, which includes all non-Caulobacter crescentus Slayer proteins.

Second, the genus of *Caulobacter crescentus* S-layer proteins is distinguished from other proteins only by functional features of the genus. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: "[i]n claims to genetic material, however a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural

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features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus" and "[a] definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." Similarly with the genus of recited fragments of a Caulobacter crescentus S-layer protein comprising a secretion signal, the specification fails to define those structural characteristics that distinguish "a Caulobacter crescentus S-layer protein" from any protein, particularly other non-*C. crescentus* S-layer proteins. In this case, the recitation of "a fragment of a Caulobacter crescentus S-layer protein which comprises a secretion signal" merely describes the "functional" features of the genus without providing any definition of the structural features of the species within the genus, i.e., the specification does not provide any structural information commonly possessed by members of the genus which distinguish the species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus. As stated in a previous Office action, the examiner knows of no correlation between the structure of a C. crescentus S-layer protein which comprises a secretion signal and the "function" of a C. crescentus S-layer protein fragment which comprises a secretion signal. It is noted the term "functional" has been written with quotations as there is no explicit recitation of a function for the first component, however, the fragment comprises a secretion signal, which implies the fragment has the ability to be secreted from a cell. In this case, the

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genus is not limited by any structural features, *i.e.*, the genus encompasses any structure of a protein that is considered to be a *Caulobacter crescentus* S-layer protein.

Applicant argues the claims are not drawn to S-layer protein fragments that include a secretion signal, which have been disclosed and claimed in US Patent 6,210,948, which allegedly teaches the characteristics of a *C. crescentus* S-layer protein fragment that include a secretion signal and how to make and use such a fragment. Applicant argues he should not be required to describe additional species with respect to a claim element that is already taught in the art.

Applicant's argument is not found persuasive. Regarding the '948 patent, applicant is reminded that each patent application is examined on its own merits. It is noted that the *C. crescentus* S-layer protein fragment as recited in the instant claims is not so limited to the *C. crescentus* S-layer protein fragment of the claims of the '948 patent. While the examiner acknowledges that representative species are disclosed in the '948 patent, which appear to be identical to the species disclosed in the instant specification, these species fail to describe all members of the recited genus for the reasons of record and the reasons stated herein.

Applicant argues that, given the alleged benefit of the claimed invention, the skilled artisan would consider the successful results disclosed in the Examples to be applicable to other *C. crescentus* S-layer protein fragments that include a secretion signal.

Applicant's argument is not found persuasive. The issue is whether the specification in view of the prior art describes the genus of first components of the

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fusion protein. Applicant's argument appears to address the issue of enablement and not written description. To the extent the argument is intended to apply to the written description rejection, the examiner maintains the position that the disclosed species fail to describe all members of the recited genus, which encompasses widely variant species as described above.

Applicant argues the instant case is distinguished from *UC California v. Eli Lilly* as the instant claimed invention is directed to cleaving insoluble fusion proteins of *C. crescentus* S-layer protein fragments containing a secretion signal, which are allegedly elements known in the art.

Applicants' argument is not found persuasive. It should be noted that the recited genus of *C. crescentus* S-layer protein fragments containing a secretion signal is not limited to those that are known in the prior art. The examiner maintains that *UC California v. Eli Lilly* is relevant to the instant case at least for the reasons stated above. Just as the court in *UC California v. Eli Lilly* found that the functional description of a genus failed to define the structural features common to all members of the genus, the "functional" characteristic of the genus of recited first components fails to define the structural features common to all members of the genus.

At least for the reasons of record and the reasons state above, the specification in view of the prior art fails to describe all members of the recited genus of *C. crescentus* S-layer protein fragments containing a secretion signal.

[9] In view of the examiner's newly stated interpretation of the terms "Caulobacter crescentus S-layer protein" and "an S-layer protein of said Caulobacter crescentus," it is

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the examiner's position that it would not constitute undue experimentation for a skilled artisan to make all methods as encompassed by the claims. The claims are limited to those fragments of S-layer proteins from a single bacterial strain, namely *C. crescentus*. Although the scope encompasses those fragments of S-layer proteins from any *C. crescentus*, including mutant *C. crescentus* strains, it is the examiner's position that it would not be undue experimentation for a skilled artisan to screen mutant strains of *C. crescentus* to isolate those S-layer protein fragments that can be successfully used in the claimed methods.

Claim Rejections - 35 USC § 103

[10] Upon reconsideration of the rejection of claims 1-6 and 9-12 under 35
U.S.C. 103(a), the rejection is withdrawn. Contrary to applicant's argument, the examiner maintains that the references teach or suggest all elements of the claimed invention and provide motivation for making the claimed fusion protein and cleaving said fusion protein at an Asp-Pro bond by acid hydrolysis. However, the examiner notes that in view of the prior art of record there does not appear to be a reasonable expectation of success that the *insoluble* fusion protein would be cleaved upon treatment at an acidic pH. While the insoluble fusion protein of Better was successfully cleaved by acid hydrolysis, this is no indication that the recited fusion protein would also be cleaved upon acid hydrolysis for the reasons that follow. At the time of the invention, one of ordinary skill in the art would have had a reasonable expectation of success for cleaving a fusion protein at an Asp-Pro bond joining two components of a *soluble* fusion protein.

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However, in this case, the fusion protein is *insoluble* and the prior art of record provides no evidence that a fusion protein of a C. crescentus S-layer protein fragment comprising a secretion signal and a heterologous protein would exhibit a three-dimensional conformation that is amenable to acid hydrolysis. In other words, it is not clear from the prior art of record that an Asp-Pro cleavage site in an insoluble fusion protein of a C. crescentus S-layer protein fragment comprising a secretion signal and a heterologous protein would be sufficiently solvent-exposed to achieve successful hydrolysis of the Asp-Pro bond or whether the Asp-Pro cleavage site would be internalized or buried within the protein such that hydrolysis is prevented. As such, it is the examiner's position that the cited references do not provide a reasonable expectation of success to one of ordinary skill in the art to make the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J. STEADMAN, PH.D

PRIMARY EXAMINER

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APPENDIX A

Qy

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Cited as reference
AD in IDS Filed 10/21/02
RESULT 4
AAR48993
TD
     AAR48993 standard; Protein; 1026 AA.
XX
AC
     AAR48993;
xx
DT
     14-SEP-1994 (first entry)
XX
DE
     rsaA S-lyaer protein.
XX
     C. crescentus; rsaA; paracrystalline; S-layer; protein; heterologous;
KW
KW
     cellulase; xylase; metallothionein; restriction site;
KW
     reading frame; fusion protein; bioreactor; toxic metal; sewage;
KW
     waste water; wood pulp suspension; cell surface; vaccine; fish.
XX
OS
     Caulobacter crescentus.
XX
     CA2090549-A.
PN
XX
     10-DEC-1993.
PD
XX
PF
     26-FEB-1993:
                    93CA-2090549.
XX
PR
     09-JUN-1992;
                    92US-0895367.
XX
     (UYBR-) UNIV BRITISH COLUMBIA.
PA
XX
ΡI
     Bingle WH, Smit J;
XX
DR
     WPI; 1994-066249/09.
DR
     N-PSDB; AAQ57972.
XX
PT
     Prodn. of heterologous polypeptides in bacteria, partic.
PT
     Caulobacter - by expression of a fusion prod. of the polypeptide
PT
     sequence and a bacterial S-layer protein gene
XX
PS
     Claim 17; Fig 6; 27pp; English.
ХX
CC
     This sequence is encoded by the C. crescentus rsaA gene and represents
CC
     the paracrystalline S-layer protein. The rsaA gene was used in the
CC
     production of the heterologous protein of the invention. The
CC
     heterologous protein is produced by cloning a polypeptide coding
CC
     sequence, eg. cellulase, xylase or a metallothionein, into a
CC
     restriction site within the rsaA gene which preserves the rsaA reading
CC
     frame and expressing the fusion sequence in Caulobacter. This S-
CC
     layer protein bacterial system can be used in bioreactors, eg. to
CC
     bind toxic metals in sewage waste water etc. or for the treatment of
CC
     wood pulp suspensions. The system can be used to produce heterologous
CC
     proteins at the cell surface for use in vaccines, partic. fish
CC
     vaccines. The S-layer protein is synthesised in large quantities and
     has a general repetitive sequence, permitting the synthesis of large
CC
CC
     amounts of heterologous protein as a fusion product and presentation at
CC
     the cell surface.
XX
SQ
     Sequence
              1026 AA;
  Query Match
                         99.2%; Score 4938; DB 15;
                                                      Length 1026;
 Best Local Similarity
                         99.4%; Pred. No. 7.9e-230;
 Matches 1020; Conservative
                                0; Mismatches
                                                      Indels
Qy
        1 MAYTTAQLVTAYTNANLGKAPDAATTLTLDAYATQTQTGGLSDAAALTNTLKLVNSTTAV 60
          14114141414141414414144144414444
Db
       1 MAYTTAQLVTAYTNANLGKAPDAATTLTLDAYATQTQTGGLSDAAALTNTLKLVNSTTAV 60
```

61 AIQTYQFFTGVAPSAAGLDFLVDSTTNTNDLNDAYYSKFAQENRFINFSINLATGAGAGA 120

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Db	61	${\tt AIQTYQFFTGVAPSAAGLDFLVDSTTNTNDLNDAYYSKFAQENRFINFSINLATGAGAGA}$	120
Qy	121	TAFAAAYTGVSYAQTVATAYDKIIGNAVATAAGVDVAAAVAFLSRQANIDYLTAFVRANT	180
Db	121	TAFAAAYTGVSYAQTVATAYDKIIGNAVATAAGVDVAAAVAFLSRQANIDYLTAFVRANT	180
Qy	181	PFTAAADIDLAVKAALIGTILNAATVSGIGGYATATAAMINDLSDGALSTDNAAGVNLFT	240
Db	181	PFTAAADIDLAVKAALIGTILNAATVSGIGGYATATAAMINDLSDGALSTDNAAGVNLFT	240
Qy	241	AYPSSGVSGSTLSLTTGTDTLTGTANNDTFVAGEVAGAATLTVGDTLSGGAGTDVLNWVQ	300
Db		${\tt AYPSSGVSGSTLSLTTRTDTLTGTANNDTFVAGEVAGAATLTVGDTLSGGAGTDVLNWVQ}$	
Qy	301	AAAVTALPTGVTISGIETMNVTSGAAITLNTSSGVTGLTALNTNTSGAAQTVTAGAGQNL	360
Db	301	AAAVTALPTGVTISGIETMNVTSGAAITLNTSSGVTGLTALNTNTSGAAQTVTAGAGQNL	360
Qу	361	TATTAAQAANNVAVDGRANVTVASTGVTSGTTTVGANSAASGTVSVSVANSSTTTTGAIA	420
Db		TATTAAQAANNVAVDGGANVTVASTGVTSGTTTVGANSAASGTVSVSVANSSTTTTGAIA	
Qу	421	VTGGTAVTVAQTAGNAVNTTLTQADVTVTGNSSTTAVTVTQTAAATAGATVAGRVNGAVT	480
Db		VTGGTAVTVAQTAGNAVNTTLTQADVTVTGNSSTTAVTVTQTAAATAGATVAGRVNGAVT	
Qy		ITDSAAASATTAGKIATVTLGSFGAATIDSSALTTVNLSGTGTSLGIGRGALTATPTANT	
Db		ITDSAAASATTAGKIATVTLGSFGAATIDSSALTTVNLSGTGTSLGIGRGALTATPTANT	
Qу		LTLNVNGLTTTGAITDSEAAADDGFTTINIAGSTASSTIASLVAADATTINISGDARVTI	
Db		LTLNVNGLTTTGAITDSEAAADDGFTTINIAGSTASSTIASLVAADATTLNISGDARVTI	
Qу		TSHTAAALTGITVTNSVGATLGAELATGLVFTGGAGRDSILLGATTKAIVMGAGDDTVTV	
Qу		SSATLGAGGSVNGGDGTDVLVANVNGSSFSADPAFGGFETLRVAGAAAQGSHNANGFTAL	
Db			
Òу		QLGATAGATTFTNVAVNVGLTVLAAPTGTTTVTLANATGTSDVFNLTLSSSAALAAGTVA	
Db			780
Qу		LAGVETVNIAATDTNTTAHVDTLTLQATSAKSIVVTGNAGLNLTNTGNTAVTSFDASAVT	840
Db	781	LAGVETVNIAATDTNTTAHVDTLTLQATSAKSIVVTGNAGLNLTNTGNTAVTSFDASAVT	840
Qу	841	GTAPAVTFVSANTTVGEVVTIRGGAGADSLTGSATANDTIIGGAGADTLVYTGGTDTFTG	900
Db	841		900
Qy	901	${\tt GTGADIFDINAIGTSTAFVTITDAAVGDKLDLVGISTNGAIADGAFGAAVTLGAAATLAQ}$	960
Db	901		960
Qу	961	YLDAAAAGDGSGTSVAKWFQFGGDTYVVVDSSAGATFVSGADAVIKLTGLVTLTTSAFAT	1020
Db	961		1020
Qу	1021	EVLTLA 1026	
Db	1021	EVLTLA 1026	